

REMARKS

The Final Office Action mailed on April 30, 2009, has been received, and carefully considered.

The rejection of claims 1-5 and 7-12 under 35 U.S.C. § 102(b) as being anticipated by Jeffrey (US 5,957,897, hereinafter "Jeffrey '897") is respectfully traversed.

The cited reference to Jeffrey '897 does not disclose or suggest Applicant's invention as claimed.

Claim 1 has been amended to further distinguish the inventive aspects of the present invention over the prior art, and particularly to make clear the difference between the disclosure in Figs. 10 to 12 of Jeffrey '897 and the presently claimed invention.

To this end, claim 1 now requires the limitation: *"wherein said plunger also has at its forward end in direction of its insertion into the body, and separate from said latch opening formations, deflectable edge members whereby it can abut and displace the piston rod and said hollow body separate from said latching formations which retain the spring barrel internal deflector means which serves to deflect said deflectable edge members of said plunger out of the path of retraction of the syringe barrel"*.

With regard to Jeffrey '897, the Examiner has stated that receiving formation 347, which is essentially a sloping ledge with a small indent and halfway down the interior of the plunger 345, discloses the *"deflectable edge members"* of the invention. The Examiner has also taken the position that latching members 375, 376 of Jeffrey '897 disclose not only the internal latching formations on the body which retain the barrel 325 against the force of the spring 323, but also the *"internal deflector means"* which serve to deflect the deflectable edge members out of the path of retraction of the barrel 325.

Referring to the attached color-coded copy of Figs. 10 to 12 of Jeffrey '897, the assembly is shown comprising a cartridge 325 with a needle 320, a piston 330 at the remote end of the cartridge contents, and a piston rod 332 connected to said piston. These parts together are equivalent to the syringe 40 of the present application. Additionally, Jeffrey '897 discloses a hollow, closed end piston actuator 345, equivalent to the plunger 30 of the present application, which fits into the hollow body 311 (equivalent to body 10 of the present invention) to the rear of the piston rod, and serves to displace the piston rod to expel cartridge/syringe contents via the needle, and also to receive the piston rod and at least a part of the cartridge 325 and its needle 320 as the cartridge/syringe is retracted at the end of contents expression (Fig. 12).

In Jeffrey '897, the piston rod 332 has splayed arms 337 near its rear end which are retained on receiving formations 347 internal to the actuator 345 which are well back from the open forward end or rim 378 of the plunger 345.

When the actuator (345) is depressed and drives the piston rod 332 forward, the chamfered rim 378 engages the latching members 375, specifically the sloping teeth 376 of same, and deflects same outwards, thereby releasing the end cap 372 of the cartridge and allowing the spring 323 to act.

At the same time, the arms 337 of the piston rod 332 are released from engagement with the receiving formations 347 to allow the spring action to retract the cartridge. However, this is not achieved, as supposed by the Examiner, by contact of the chamfered rim 378 against the latching member 375 merely jolting the arms 337 free by some sort of outward deflection of the formations 347. That simply would not happen because the

tolerance is very close and the actuator 345 is a close sliding fit in the outer body 311 thereby preventing any outward deformation of the actuator 345.

Also, the retention of the arms 337 by the receiving formation 347 needs to be secure otherwise the piston rod 332 might not be reliably driven forward by the plunger 345.

In other words, if deformation/deflection of the receiving formation 347 is possible (as suggested by the Examiner), the whole mechanism would be so unreliable that it would not be appropriate in a drug delivery device where virtually 100% reliability is demanded.

In fact, arms 337 of the Jeffrey '897 piston rod 332 are released from the formations 347 by engagement of the splayed arms 337 with the rear end of cartridge 325, which happens at virtually the same time as the rim 378 is deflecting the latching members 375. This is not specifically explained in Jeffrey '897 in relation to Fig. 10, 11, 12 of Jeffrey '897 because it has already been described in relation to the earlier embodiment, of which the devices shown in Figs. 10, 11, 12 are variants.

Thus, in relation to Figs. 1 to 4 of Jeffrey '897, the release of arms 337 from receiving formations 347 is explained at col. 7, lines 7 to 11, of the reference. However it is noted there, and also at col. 6, lines 12 to 21, and col. 2, line 50 to col. 3, line 48, that a triggering ring 160 is provided in the first embodiment because reliance on the end of the cartridge to reliably inwardly deflect arms 137 is inadequate for the reliability required in a drug delivery device. Thus, the version illustrated in Figs. 10 to 12, which does not employ such a triggering ring, is not in practice commercially satisfactory.

It should also be noted that Jeffrey '897 discloses that the piston rod 332 has *"deflectable arms that extend sideways further than the side walling of the cartridge, the piston actuator having receiving formations with which the deflectable arms make temporary*

driving engagement until the deflectable arms are engaged and released during bias driven movement of the piston actuator toward the bottom portion of the body before a bias driven movement of the cartridge toward the bottom portion of the body” (see original claims 1 and 15 of Jeffrey '897).

Therefore, the teaching in Jeffrey '897 is that the arms 337 are positively engaged in order to be deflected and released. The arms 337 are not merely jolted free of the receiving formations 347.

Turning now to the present application, in condition in which the device is supplied (shown in Figure 1) the piston rod 45 does not extend in the same way into the hollow cavity of the plunger 30, as the piston rod 332 does in Jeffrey '897. The piston rod 45 of the present invention does not have deflectable arms which are retained on formations which are halfway down the cavity of the plunger 30. Instead, the rear end flange of the piston rod 45 is driven by means of the deflectable edge members 33 at the forward end of the plunger 30. Therefore, at the forward end of the plunger 30 there are both latch opening formations 34, which are equivalent to the chamfered rim 378 of Jeffrey '897 and serve to deflect the latching formations 18, 19 of the outer body 10, as well as the edge members 33 which serve by contact with the end of the piston rod 45 to drive (it) the piston rod forward.

In the illustrated embodiment, the latch opening formations 34 alternate with the deflectable edge members 33 at opposing circumferential locations (see Figs. 6 and 7) at the forward end of the plunger 30. These edge members 33 are subsequently, during operation of the device, deflected by internal deflector formations 22 provided at appropriate positions inside the body 10. These deflector formations 22 are separate from the known latching formations 18, 19 which serve to hold the original syringe 40 against the bias of spring 20.

The amended claim 1 now clearly recites that the plunger has latch opening formations **34** at its forward end, which correspond to chamfered rim **378** of Jeffrey '897. Furthermore, amended claim 1 now clearly recites that the plunger additionally has, also at its forward end, separate from latching formations **34**, deflectable edge members **33** which abut and displace the piston rod **45** and that the hollow body has, separate from latching formations **18, 19**, internal deflector means **22** which deflect said deflectable edge members **33** out of the path of retraction of the syringe barrel.

Therefore, by these amendments, Applicant believes that a clear structural distinction has now been made over the prior art,

The arrangement disclosed and claimed in the present application has a clear advantage over the arrangement shown in Figs. 10 to 12 of Jeffrey '897, in that in the latter, the end of the cartridge **325** would not reliably inwardly deflect the arms **337** exactly at the correct moment to allow retraction of the cartridge and piston rod under bias of the released spring **323**, thus not reliably retracting the needle, which is the whole purpose of this arrangement. In contrast, in Applicant's present device, the internal deflector projections **22** provided in the body **10** reliably deflect the edge members **33**.

Another important distinction and advantage of the presently claimed arrangement is that the piston rod does not have splayed deflectable arms whereby temporary drive connection to the plunger is made. As explained in the present description, particularly at page 1, lines 5 to 6 and 9 to 12; page 2, lines 3 to 7; and page 3, lines 4 to 6 and 14 to 16, the present arrangement is specifically designed to accept proprietary miniature syringes, which incorporate their own piston rod which will not have such splayed arms.

Accordingly, the present device using the deflectable edge members 33 allows a practitioner to assemble such syringe into the outer body itself and reliably use the assembly to administer contents and achieve desired needle retraction at the end of contents expression from the syringe.

In view of all of the above, it is Applicant's position that Jeffrey '897 fails to disclose or suggest every limitation of independent claim 1, and claims 2-5 and 7-12 which are dependent thereon. Accordingly, it is believed that the rejection under 35 U.S.C. 102(b) is unsustainable and should be favorably reconsidered and withdrawn.

It is believed that the present application is now in condition for allowance, and an early allowance to this effect is respectfully urged. If any final points remain that can be clarified by telephone, Examiner Campbell is encouraged to contact Applicant's attorney at the number indicated below.

Respectfully submitted



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